

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<b>TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371</b>		ATTORNEY'S DOCKET NUMBER <b>06019/HG</b>
INTERNATIONAL APPLICATION NO. <b>PCT/JP2004/010542</b>	INTERNATIONAL FILING DATE <b>16 JULY 2004</b>	U.S. APPLICATION NO. (If known, see 37 CFR 1.5) <b>10/564,579</b>
TITLE OF INVENTION <b>THERAPEUTIC AGENT FOR PRURITUS COMPRISING PIPERIDINE DERIVATIVE AS ACTIVE INGREDIENT</b>		PRIORITY DATE CLAIMED <b>17 JULY 2003</b>
APPLICANT(S) FOR DO/EO/US <b>Daisuke SHII; Tomoko ODA; Hideki MIYAKE; Manabu FUJITA</b>		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
1. <input type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a submission under 35 U.S.C. 371.		
2. <input checked="" type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a submission under 35 U.S.C. 371.		
3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.		
4. <input type="checkbox"/> The US has been elected (Article 31).		
5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) <ul style="list-style-type: none"> <li>a. <input type="checkbox"/> Is attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> has been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> Is not required, as the application was filed in the United States Receiving Office (RO/US).</li> </ul>		
6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). <ul style="list-style-type: none"> <li>a. <input type="checkbox"/> Is attached hereto.</li> <li>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</li> </ul>		
7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) <ul style="list-style-type: none"> <li>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> have been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</li> <li>d. <input type="checkbox"/> have not been made and will not be made.</li> </ul>		
8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).		
9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).		
10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).		
<b>Items 11 to 20 below concern document(s) or information included:</b>		
11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.		
12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.		
13. <input type="checkbox"/> A preliminary amendment.		
14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.		
15. <input type="checkbox"/> A substitute specification.		
16. <input type="checkbox"/> A power of attorney and/or change of address letter.		
17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821-1.825.		
18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).		
19. <input type="checkbox"/> A second copy of the English language translation of the International application under 35 U.S.C. 154(d)(4).		
20. <input checked="" type="checkbox"/> Other items or information:		

RESPONSE TO NOTICE OF MISSING REQUIREMENTS

Express Mail Label No. EV 919 339 055 us

DATE OF DEPOSIT: JUNE 2, 2006

I hereby certify that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above with sufficient postage, and is addressed to the Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

*Dorothy DeFrancesco*  
Dorothy DeFrancesco

U.S. APPLICATION NO. (if known, see 37 CFR 1.5) <b>10/564,579</b>		INTERNATIONAL APPLICATION NO. <b>PCT/JP2004/010542</b>		ATTORNEY'S DOCKET NUMBER <b>06019/HG</b>	
The following fees have been submitted				<b>CALCULATIONS</b>	<b>PTO USE ONLY</b>
21. <input type="checkbox"/> Basic national fee..... <b>\$300</b>				\$	
22. <input type="checkbox"/> Examination fee If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4)..... <b>\$0</b> All other situations..... <b>\$200</b>				\$	
23. <input type="checkbox"/> Search fee Search fee (37 CFR 1.445(a)(2)) has been paid on the International application to the USPTO as an International Searching Authority..... <b>\$100</b> International Search Report prepared and provided to the Office..... <b>\$400</b> All other situations..... <b>\$500</b>				\$	
<b>TOTAL OF 21, 22 and 23 =</b>				\$	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is <b>\$250</b> for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
- 100 =	/50 =		x \$250	\$	.00
Surcharge of <b>\$130.00</b> for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(h)).				\$	.00
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$	
Total claims	- 20 =		x \$ 50	\$	.00
Independent claims	- 3 =		x \$200	\$	.00
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$360	\$	
<b>TOTAL OF ABOVE CALCULATIONS =</b>				\$	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.					
<b>SUBTOTAL =</b>				\$	
Processing fee of <b>\$130.00</b> for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).				\$	.00
<b>TOTAL NATIONAL FEE =</b>				\$	.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). <b>\$40.00</b> per property				\$	
<b>TOTAL FEES ENCLOSED =</b>				\$	
				Amount to be refunded:	\$ .00
				Amount to be charged:	\$ .00
a. <input type="checkbox"/> A check in the amount of \$ _____ to cover the above fees is enclosed. b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <b>06-1378</b> . A duplicate copy of this sheet is enclosed. d. <input type="checkbox"/> Fees are to be charged to a credit card. <b>WARNING:</b> Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.					
<b>NOTE:</b> Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.					
SEND ALL CORRESPONDENCE TO: <b>CUSTOMER NO. 01933</b> Richard S. Barth Frishauf, Holtz, Goodman & Chick P.C. 220 5TH AVE FL 16 NEW YORK NY 10001-7708					
				SIGNATURE	
				<b>Richard Barth</b>	
				NAME	
				<b>28,180</b>	
				REGISTRATION NUMBER	

**IN THE UNITED STATES PATENT  
AND TRADEMARK OFFICE**

Serial No. : 10/564,579  
Applicants : Daisuke SHII et al.  
Filed : January 13, 2006  
For : THERAPEUTIC AGENT FOR  
PRURITIS..  
Docket No. : 06019/HG  
Confirm. No.: 2031  
Customer No.: 01933

**RESPONSE TO NOTICE OF MISSING REQUIREMENTS**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**MAIL STOP PCT**

S I R :

We received the NOTIFICATION OF MISSING REQUIREMENTS UNDER  
35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE  
(DO/EO/US) mailed May 23, 2006 requiring a missing Oath or  
Declaration by July 23, 2006. However, on May 10, 2006, the  
executed DECLARATIONS with the proper fees were filed by Express  
Mail in the USPTO.

Enclosed herewith are copies of the PTO NOTICE, the two  
executed DECLARATIONS, a paper entitled SUBMISSION OF SIGNED

Express Mail Mailing Label  
No.: EV 919 339 055 US  
Date of Deposit: June 2, 2006  
I hereby certify that this paper is  
being deposited with the United States  
Postal Service "Express Mail Post  
Office to Addressee" service under  
37 CFR 1.10 with sufficient postage  
on the date indicated above and is  
addressed to:  
MAIL STOP PCT  
Commissioner for Patents.  
P.O. Box 1450  
Alexandria, VA 22313-1450

  
Dorothy DeFrancesco

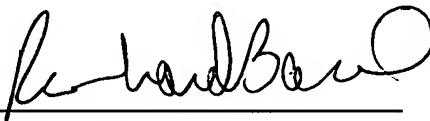
In the event that this Paper is late  
filed, and the necessary petition  
for extension of time is not filed  
concurrently herewith, please consider  
this as a Petition for the requisite  
extension of time, and to the extent  
not tendered by check attached hereto,  
authorization to charge the extension  
fee, or any other fee required in  
connection with this Paper to  
Account No. 06-1378.

DECLARATIONS AND ASSIGNMENT and the postcard receipt stamped with the received date of 10 MAY 2006.

Please expedite the Notice of Acceptance of Application Form.

Frishauf, Holtz, Goodman  
& Chick, P.C.  
220 Fifth Ave., 16th Floor  
New York, NY 10001-7708  
Tel. No.: (212) 319-4900  
Fax No.: (212) 319-5101  
E-Mail Address: BARTH@FHGC-LAW.COM  
RSB/ddf

Respectfully submitted,

  
Richard S. Barth  
REG. NO. 28,180

Encs.

AP3 Rec'd PCT/PTO 10 MAY 2006

DOCKET NO.: 06019/HG - Daisuke ISHII et al.

Serial No. 10/564,579

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/  
ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION  
UNDER 35 U.S.C. 371: (SUBSEQUENT SUBMISSION);  
PAPER ENTITLED "SUBMISSION OF SIGNED DECLARATIONS";  
EXECUTED DECLARATION DATED MARCH 2, 2006 (TWO PAGES);  
EXECUTED DECLARATION DATED MARCH 8, 2006 (TWO PAGES);  
FORM PTO-2038 IN THE AMOUNT OF \$130.  
EXECUTED ASSIGNMENT, FORM PTO-1595 AND FORM  
PTO-2038 IN THE AMOUNT OF \$40.

EXPRESS LABEL EV 842 304 565 US  
DATE OF DEPOSIT: MAY 10, 2003

RSB/ddf



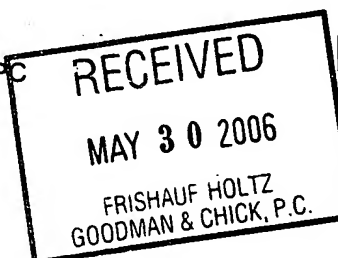
## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/564,579	Daisuke Shii	06019/HG

01933

FRISHAUF, HOLTZ, GOODMAN & CHICK, PC  
 220 Fifth Avenue  
 16TH Floor  
 NEW YORK, NY 10001-7708



INTERNATIONAL APPLICATION NO.	
PCT/JP04/10542	
I.A. FILING DATE	PRIORITY DATE
07/16/2004	07/17/2003

CONFIRMATION NO. 2031

371 FORMALITIES LETTER



\*OC000000018894664\*

Date Mailed: 05/23/2006

*Missing Parts*  
*due: July 23, 2006*

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 01/13/2006
- English Translation of the IA filed on 01/13/2006
- Copy of the International Search Report filed on 01/13/2006
- Preliminary Amendments filed on 01/13/2006
- Information Disclosure Statements filed on 04/07/2006
- Request for Immediate Examination filed on 01/13/2006
- U.S. Basic National Fees filed on 01/13/2006
- Priority Documents filed on 01/13/2006
- Specification filed on 01/13/2006
- Claims filed on 01/13/2006
- Abstracts filed on 01/13/2006

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.

**ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

WINSTON M ALVARADO

Telephone: (703) 308-9140 EXT 206

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/564,579	PCT/JP04/10542	06019/HG

FORM PCT/DO/EO/905 (371 Formalities Notice)

**IN THE UNITED STATES PATENT  
AND TRADEMARK OFFICE**

Serial No. : 10/564,579  
Applicants : Daisuke SHII et al.  
Deposited : January 13, 2006  
For : THERAPEUTIC AGENT FOR  
PRURITUS COMPRISING  
PIPERIDINE DERIVATIVE AS  
ACTIVE INGREDIENT

Docket No. : 06019/HG

Customer No.: 01933

Confirm. No.: 2031

**SUBMISSION OF SIGNED DECLARATIONS  
AND ASSIGNMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**MAIL STOP PCT**

S I R :

The NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371  
IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) has not  
yet been received in the above-identified application.

However, to expedite processing, enclosed herewith is an  
executed Declaration dated March 2, 2006 executed by the  
inventor, Manabu FUJITA, and an executed Declaration dated  
March 8, 2006 executed by the inventors Daisuke ISHII, Tomoko ODA

Express Mail Mailing Label  
No.: EV 842 304 565 US  
Date of Deposit: May 10, 2006  
I hereby certify that this paper is  
being deposited with the United States  
Postal Service "Express Mail Post  
Office to Addressee" service under  
37 CFR 1.10 with sufficient postage  
on the date indicated above and is  
addressed to:  
MAIL STOP PCT  
Commissioner for Patents,  
P.O. Box 1450  
Alexandria, VA 22313-1450

  
Dorothy DeFrancesco

In the event that this Paper is late  
filed, and the necessary petition  
for extension of time is not filed  
concurrently herewith, please consider  
this as a Petition for the requisite  
extension of time, and to the extent  
not tendered by check attached hereto,  
authorization to charge the extension  
fee, or any other fee required in  
connection with this Paper to  
Account No. 06-1378.



and Hideki MIYAKE. Please enter the enclosed Declarations in the file of the above-identified application.

Enclosed is a Form PTO-2038 in the amount of \$130 as the surcharge for filing the Declarations on a date later than the deposit date of the application.

Also enclosed is an executed Assignment and Form PTO-1595 and a check for \$40 to cover the Assignment recordation fee.

Respectfully submitted,



---

RICHARD S. BARTH  
REG. NO. 28,180

FRISHAUF, HOLTZ, GOODMAN & CHICK, P.C.  
220 FIFTH AVENUE, 16th FLOOR  
NEW YORK, NEW YORK 10001-7708  
Tel. Nos. (212) 319-4900  
(212) 319-4551/Ext. 219  
Fax No. (212) 319-5101  
E-Mail Address: BARTH@FHGC-LAW.COM  
RSB/ddf

Encs.: (1) Executed Declaration dated March 2, 2006  
(2) Executed Declaration dated March 8, 2006  
(3) Form PTO-2038 in the amount of \$130  
(4) Executed Assignment  
(5) Form PTO-2038 in the amount of \$40